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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,819	05/19/2000	Frank P. Luyten	NIH0099.001C1	1648
45311	7590	06/02/2005	EXAMINER	
KNOBBE, MARTENS, OLSON & BEAR, LLP			ROMEO, DAVID S	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1647	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/574,819	<b>Applicant(s)</b> LUYTEN ET AL.	
	<b>Examiner</b> David S. Romeo	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 27-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

The amendment filed 03/08/2005 has been entered. Claims 27-32 are pending and being examined.

5 **Maintained Formal Matters, Objections, and/or Rejections:**

***Claim Rejections - 35 USC § 102***

Claim 27 is rejected under 35 U.S.C. 102(a) as being anticipated by Storm (38, cited by Applicants).

***Claim Rejections - 35 USC § 103***

10 Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storm (38, cited by Applicants) and Neidhardt (9, cited by Applicants).

Applicants argue that the declaration under 37 C.F.R. § 1.131 filed 07/12/2004 is effective to overcome the Storm reference because the declaration (paragraph 6 and Exhibit B) shows that the inventors identified two novel members (CDMP-1 and CDMP-2) of the BMP family, which are members of the TGF- $\beta$  superfamily. Applicants argue that although CDMP-1 falls outside the subclass of CDMP-2, both species are members of a common CDMP class. Applicants argue that one of ordinary skill in the art would expect that the bovine CDMP-2 species would be accompanied by other co-species, such as human, zebrafish, or Xenopus CDMP-2, to form the class of CDMP-2s, as CDMP-1 is accompanied by the CDMP-2 co-species to assemble into the class of CDMPs. Applicants argue that Applicants possessed two species, CDMP-1 and CDMP-2, that define a class of CDMPs, that bovine CDMP-2 anticipates a genus

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of CDMP-2s, and that the evidence provides an ample basis for inferring that the invention has generic applicability.

Applicants' arguments have been fully considered but they are not persuasive. The present claims are directed to polynucleotides encoding a genus of polypeptides comprising the amino acid sequence of SEQ ID NO: 24. In the declaration under 37 CFR 1.131 filed 07/12/2004 Declarant states (paragraph 1) that the claimed invention does not encompass GDF-5 (CDMP-1). Therefore, the argument that CDMP-1 is accompanied by the CDMP-2 co-species to assemble into the class of CDMPs does not show prior completion of one or more species which put Applicants in possession of the claimed genus prior to the Storm reference.

In the declaration under 37 CFR 1.131 filed 07/12/2004 Declarant states (paragraph 4) that CDMP-1 is designated as "cdmp4matORF" and that CDMP-2 is designated as "bmp3xmatORF" in Exhibit B. The "bmp3xmatORF" species in Exhibit B is the only species in the declaration that is encompassed by the genus of polypeptides encoded by the claimed nucleic acid molecule. It is noted that the "bmp3xmatORF" is a species that is different from the GDF-6 species disclosed by Storm. Proof of prior completion of a species different from the species of the reference or activity will be sufficient to overcome a reference indirectly under 37 CFR 1.131 if the species shown in the reference or activity would have been obvious in view of the species shown to have been made by the applicant. Although the bovine species of CDMP-2 designated as "bmp3xmatORF" would suggest the presence of a mouse CDMP-2, the declaration does not make obvious the mouse species of CDMP-2 (GDF-6) shown in the Storm reference because the declaration does not provide any evidence that would lead one of ordinary skill in the art to SEQ ID NO: 24 or indicate that SEQ ID NO: 24 should be present in the mouse species

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of CDMP-2 (GDF-6) shown in the Storm reference. The declaration does not expressly describe SEQ ID NO: 24 or the SHLEP motif. Nor does the declaration suggest the presence of SEQ ID NO: 24 in the mouse CDMP-2. Exhibit B does not provide evidence that Applicants conceived of the claimed genus of polypeptides comprising the amino acid sequence of SEQ ID NO: 24.

- 5 Nor does the declaration provide evidence that one of ordinary skill in the art would reasonably expect a mouse species of CDMP-2 to comprise SEQ ID NO: 24. The facts and all of the evidence do not support the conclusion the species of CDMP-2 (GDF-6) shown in the Storm reference would have been obvious in view of the CDMP-2 species (bmp3xmatORF) shown to have been made by the applicants.

10

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

- A shortened statutory period for reply to this final action is set to expire THREE
- 15 MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37
- CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,
- 20 however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

DSR  
MAY 27, 2005